REMARKS

The Abstract has been amended to more unmistakably comply with the requirements of MPEP §608.01(b).

Claims 1, 4 and 6 have been amended; claims 2, 3, 5 and 7-12 have been cancelled; and claim 13 has been added. Accordingly, upon entry of the above amendments, claims 1, 4, 6 and 13 will be pending an under consideration in the application.

Applicant expressly reserves the right to introduce cancelled claims 9-12, which were withdrawn from consideration pursuant to a restriction requirement, or similar claims, in a divisional application.

Objection to the Specification

The Abstract of the disclosure was objected to on ground that it consisted of more than 15 lines of text and more than 150 words. The Abstract was previously rewritten to comply with the requirements of MPEP §608.01(b) in a Preliminary Amendment filed December 5, 2005. In this Amendment, the Abstract was rewritten to include fewer than 15 lines of text and fewer than 150 words. However, in order to unquestionably comply with the requirements of MPEP §608.01(b), the Abstract has again been amended to include fewer than 8 lines of text, and fewer than 80 words.

Objection to Claim 7

Claim 7 has been objected to because the word "comprising" is improper and should be removed.

This objection has been obviated by cancellation of claim 7.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claim 4 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the rejection states that the phrase "in that porous apatite derivative has a zinc substitution rate or zinc content rate of 0.1 to 2.0" is unclear because it refers to a rate

of substitution and does not clearly convey the amount of zinc required to be present in the claimed microparticles.

This rejection has been overcome by the amendment to claim 4 in which the allegedly indefinite language has been replaced with the definite language that "the number of atoms of zinc contained in the zinc-containing porous hydroxyapatite is 0.1 to 2.0 relative to 10 atoms of calcium of the porous hydroxyapatite." Support for this amendment can be found at page 8, lines 15-16 of the specification which expressly states that the number of zinc atoms relative to 10 calcium atoms "is preferably 0.1 to 5.0, more preferably 0.1 to 2.0."

Claim Rejections Under 35 U.S.C. §102

Claims 1-8 stand rejected under 35 U.S.C. §102(a) as being anticipated by WO 04/000270 (hereinafter referred to as "Mizushima et al. - WO"), or alternatively under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2006/0093670 (hereinafter referred to as "Mizushima - U.S.").

The rejections based on Mizushima - WO and Mizushima - U.S. (which are substantively identical) have been overcome by the above amendments in which the requirement for a porous apatite derivative has been replaced with the requirement for "a zinc-containing porous-hydroxyapatite which is formed by partially substituting calcium atoms of porous hydroxyapatite with zinc." The applied Mizushima - WO and Mizushima - U.S. references only disclose ordinary hydroxyapatite, not a hydroxyapatite in which calcium atoms in the hydroxyapatite structure have been substituted with zinc atoms.

The invention as claimed is characterized in that zinc is contained in the porous hydroxyapatite itself and a drug other than human growth hormone and zinc chloride are absorbed to the zinc-containing porous hydroxyapatite.

The zinc-containing porous hydroxyapatite as claimed exhibits extremely large absorption rates of a drug other than human growth hormone. The larger absorption rates provide an enhanced effect in which the total dose of a sustained release preparation can be reduced.

The applied Mizushima - WO and/or Mizushima - U.S. references do not teach or suggest a zinc-containing porous hydroxyapatite as claimed, and do not provide any teaching that would

cause the person of ordinary skill in the art to modify the Mizushima - WO and/or Mizushima U.S. compositions so that calcium atoms in the hydroxyapatite are replaced with zinc atoms, as required by the claims. Accordingly, the rejection should be withdrawn.

Claims 1 and 7-8 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0180091 (hereinafter referred to as "Lin").

It is submitted that the currently-pending claims distinguish over the teachings of Lin for substantially the reasons set forth above. More specifically, Lin does not teach, suggest, or provide any motivation or reason for using a "zinc-containing porous hydroxyapatite which is formed by partially substituting calcium atoms of porous hydroxyapatite with zinc." Accordingly, the rejection based on Lin has been overcome and should be withdrawn.

Double Patenting Rejection

Claims 1-8 stand provisionally rejected on grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7, 11, 18, 24 and 25 of co-pending Application 10/516,122 (hereinafter referred to as "co-pending '122").

It is submitted that this rejection has been overcome for the reasons generally set forth above with respect to the prior art rejections. More specifically, the claims of co-pending '122 do not make the currently claimed invention obvious. More specifically, the requirement for a sustained-release microparticle preparation of a drug other than human growth hormone characterized in having a water-soluble bivalent metal compound and a drug other than human growth hormone absorbed "to a zinc-containing porous hydroxyapatite which is formed by partially substituting calcium atoms of porous hydroxyapatite with zinc" is not obvious from the claims of co-pending '122. Accordingly, the double patenting rejection has been overcome and should be withdrawn.

CONCLUSION

In view of the above amendments and remarks, it is submitted that the application is in condition for allowance and Notice of the same is requested.

Respectfully submitted,

November 6, 2009
Date

/Gunther J. Evanina/
Gunther J. Evanina
Registration No. 35502
Price, Heneveld, Cooper, Dewitt & Litton, LLP
695 Kenmoor, S.E.
Post Office Box 2567
Grand Rapids, Michigan 49501
(616) 949-9610

GJE:kjc